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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,407	01/24/2002	Lydie Meheus	INNS:011-1 11362.0011.DVU	3304
7590	07/29/2005		EXAMINER ZEMAN, ROBERT A	
Patricia A. Kammerer HOWREY SIMON ARNOLD & WHITE, LLP 750 Bering Drive Houston, TX 77057-2198			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/056,407

Applicant(s)

MEHEUS ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,11-13 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,7-9,11-13 and 23-36 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part), 23-26 (in part) and 35-36, drawn to branched peptides, classified in class 530, subclass 300.
- II. Claims 1 (in part), 23-26 (in part) and 35-36, drawn to cyclized peptides, classified in class 530, subclass 317.
- III. Claim 7 and 8, drawn to methods of chemically synthesizing branched peptides, classified in class 530, subclass 333.
- IV. Claim 9, 11 and 27, drawn to methods of recombinantly producing branched peptides, classified in class 435, subclass 69.1.
- V. Claim 7 and 8, drawn to methods of chemically synthesizing cyclized peptides, classified in class 530, subclass 333.
- VI. Claim 9, 11 and 27, drawn to methods of recombinantly producing cyclized peptides, classified in class 435, subclass 69.1.
- VII. Claim 12, drawn to antibodies to branched peptides, classified in class 530, subclass 387.1.
- VIII. Claim 12, drawn to antibodies to cyclized peptides, classified in class 530, subclass 387.1.
- IX. Claim 13, drawn to anti-idiotypic antibodies to antibodies against antibodies to branched peptides, classified in class 530, subclass 387.2.

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- X. Claim 13, drawn to anti-idiotypic antibodies to antibodies against antibodies to cyclized peptides, classified in class 530, subclass 387.2.
- XI. Claim 28, drawn to branched peptides bound to a toxin molecule, classified in class 424, subclass 236.1.
- XII. Claim 28, drawn to cyclized peptides bound to a toxin molecule, classified in class 424, subclass 236.1.
- XIII. Claims 30-31, drawn to antibodies to branched peptides bound to a toxin molecule, classified in class 424, subclass 236.1.
- XIV. Claims 30-31, drawn to antibodies to cyclized peptides bound to a toxin molecule, classified in class 424, subclass 236.1.
- XV. Claims 32-34, drawn to kits comprising branched peptides bound to a solid support, classified in class 435, subclass 808.
- XVI. Claims 32-34, drawn to kits comprising cyclized peptides bound to a solid support, classified in class 435, subclass 808.

#### **Sequence Election Requirement Applicable to Groups I and II**

In addition, Groups I and II detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO. (See MPEP 803.04) if either Group I or Group II is elected.

**Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election.**

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-II and VII-XVI are each separate and distinct from each other, as they comprise differing biochemical and immunological entities having differing properties and uses. In the instant case Inventions I-II are drawn to differing classes of peptides, while Inventions VII-X are drawn to differing types of antibodies, Inventions XI and XII are drawn to differing classes of peptides bound to a toxin, Inventions XIII-XIV are drawn to differing classes of antibodies bound to a toxin and Inventions XV and XVI are drawn to kits comprising differing classes of peptides bound to a solid support..

Inventions II-VI are separate and distinct as they are drawn to differing methods with differing steps and differing goals and utilizing differing reagents.

Inventions I and VII-XVI are each separate and distinct from Inventions III and V, as the compositions of Inventions I and VII-XVI cannot be used in (or made by) the methods of Inventions III or V.

Inventions II and VII-XVI are each separate and distinct from Inventions IV and VI, as the compositions of Inventions II and VII-XVI cannot be used in (or made by) the methods of Inventions IV or VI.

Invention I is related to Inventions III and V as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case said peptides can be made using recombinant methodologies.

Invention II is related to Inventions IV and VI as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

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claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case said peptides can be made chemical synthesis methodologies.

Because these inventions are distinct for the reasons given above and the search required for the various groups would not be coextensive in scope, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

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821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

See MPEP § 804.01.

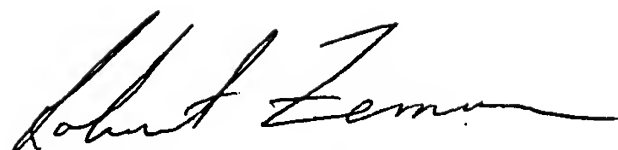
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Robert A. Zeman", with a stylized, flowing script.

**ROBERT A. ZEMAN**  
**PATENT EXAMINER**

July 26, 2005